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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,007	11/20/2003	Randolph Mellus Johnson	DURE-007CON2	9101

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,007	JOHNSON ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-91* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48-91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/13/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of preliminary amendment, filed 04/20/2004; and IDS, filed 08/13/2005.

Claims 48-91 are pending and included in the prosecution.

Priority

1. This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This is a continuation of Application No. 10/306,727, filed 11/26/2002 and matured to Patent No. 6,689,373; which is a continuation of Application No. 09/522,535, filed 03/10/2000 and matured to Patent No. 6,541,021." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 48-91 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23, 34-63 of U.S. Patent No. 6,541,021. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to method for providing analgesia by delivering fentanyl using a convective device that can be implanted (claim 58) and the conflicting claims of the issued patents are directed to the same subject matter which is method for treating pain by delivering fentanyl using implanted pump. The instantly claimed implantable convective device is generic for the pump device. Therefore it would have been obvious to one having ordinary skill in the art to use any implantable convective device to deliver fentanyl to relieve pain.

4. Claims 48-91 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,689,373. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to method for providing analgesia by delivering fentanyl using a convective device that can be implanted (claim 58) and the conflicting claims of the issued patents are directed to the same subject matter which is method for treating pain by delivering fentanyl using implanted device

comprising reservoir containing fentanyl. The instantly claimed implantable convective device is generic for the device comprising reservoir containing fentanyl. Therefore it would have been obvious to one having ordinary skill in the art to use any implantable convective device to deliver fentanyl to relieve pain.

5. Claims 48-91 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-17, 24-27 of U.S. Patent No. 6,35,194. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to method for providing analgesia by delivering fentanyl using a convective device that can be implanted (claim 58) and the conflicting claims of the issued patents are directed to the same subject matter which is method for treating pain by delivering fentanyl using implanted device comprising reservoir containing fentanyl. The instantly claimed implantable convective device is generic for the device comprising reservoir containing fentanyl. Therefore it would have been obvious to one having ordinary skill in the art to use any implantable convective device to deliver fentanyl to relieve pain.

6. Claims 48-91 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of copending Application No. 11/044,521. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to method for providing analgesia by delivering fentanyl using a convective device that

can be implanted (claim 58) and the conflicting claims of the copending application are directed to the same subject matter which is method for treating pain by delivering fentanyl using implanted device. The instantly claimed implantable convective device is a species for the generic implantable device for delivering fentanyl that claimed by copending application. Therefore the instant claims anticipate the implantable device claimed by the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 48-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,412,139 ('139) in view of US 5,980,927 ('927).

US '139 teaches osmotic device for controlled and continuous delivery of beneficial drug over a prolonged period of time to produce systemic effect (col.1, lines 50-60; col.7, lines 9-10). The device can be implanted (col.4, line 15). Analgesics can be delivered by this device.

US '139 does not teach fentanyl in particular to be delivered by the osmotic device, nor its amount in the device and its delivery rates.

US '927 teaches method for continuous administration of analgesics from implantable device for prolonged period of time up to several months (abstract; col.6, lines 66-67). Fentanyl is the preferred analgesic because of its high potency (col.4, lines 38-43).

The amount and delivery rate of the active agent do not impart patentability to the claims, absent evidence to the contrary. It is within the skilled artisan to manipulate the amount of the active agent to achieve a specific delivery profile according to specific patient need.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the implantable osmotic delivery device disclosed by US '139 that deliver analgesics continuously for prolonged period, and replace the

analgesic drug by fentanyl disclosed by US '927, motivated by the teaching of US '927 that fentanyl is a preferred analgesic because of it high potency, with reasonable expectation of the having implantable osmotic delivery device that continuously deliver fentanyl for prolonged time to relieve pain in patient in need for such treatment.

10. Claims 48-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,287,295 ('295) in view of US 5,980,927 (927).

US '295 teaches osmotic delivery system for controlling the delivery rate of drugs (abstract; col.5, line 55). The device is implantable (col.15, lines 40-41; col.16, lines 39, 48-49; col.18, lines 32-40). The device provides prolonged delivery up to 120 days (col.18, lines 43-45). Analgesics can be delivered by this device (col.19, line 3).

US '295 does not teach fentanyl in particular to be delivered by the osmotic device, nor its amount in the device and its delivery rates.

US '927 teaches method for continuous administration of analgesics from implantable device for prolonged period of time up to several months (abstract; col.6, lines 66-67). Fentanyl is the preferred analgesic because of its high potency (col.4, lines 38-43).

The amount and delivery rate of the active agent do not impart patentability to the claims, absent evidence to the contrary. It is within the skilled artisan to manipulate the amount of the active agent to achieve a specific delivery profile according to specific patient need.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the implantable osmotic delivery device disclosed by US '295 that deliver analgesics continuously for prolonged period, and replace the analgesic drug by fentanyl disclosed by US '927, motivated by the teaching of US '927 that fentanyl is a preferred analgesic because of it high potency, with reasonable expectation of the having implantable osmotic delivery device that continuously deliver fentanyl for prolonged time to relieve pain in patient in need for such treatment.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,728,396 disclosed implantable convective device that deliver active agent for prolonged period up to 2 years.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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ISIS GHALI
PATENT EXAMINER